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Other items or information: Form PCT/IB/308

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ATTORNEY'S DOCKET NUMBER 1920/47784

FORM PTO-1390 (REV 5-93) TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING PLICATION NO (if known, see 37 CFR 1 5) A FILING UNDER 35 U.S.C. 371 INTERNATIONAL APPLICATION NO. INTERNATIONAL FILING DATE PCT/EP97/06315 **12 November 1997 13 November 1996** TITLE OF INVENTION ARTIFICIAL JOINT, IN PARTICULAR ENDOPROSTHESIS FOR REPLACING NATURAL JOINTS APPLICANT(S) FOR DO/EO/US Dietmar KUBEIN-MEESENBURG, Hans NAEGERL Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information: This is **FIRST** submission of items concerning a filing under 35 U.S.C. 371. This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371 This express request to begin national examination procedures (35 U.S.C. 371(f) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1). A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date. 5. X A copy of the International Application as filed (35 U.S.C. 371(c)(2) is transmitted herewith (required only if not transmitted by the International Bureau). X has been transmitted by the International Bureau is not required, as the application was filed in the United States Receiving Office (RO/US) A translation of the International Application into English (35 U.S.C. 371(c)(2). Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) are transmitted herewith (required only if not transmitted by the International Bureau). have been transmitted by the International Bureau. have not been made; however, the time limit for making such amendments has NOT expired. X have not been made and will not be made. A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3). An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (unexecuted). 10. X A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). Item 11. to 16. below concern other document(s) or information included: An Information Disclosure Statement under 37 CFR 1.97 and 1.98. An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. X A FIRST preliminary amendment. A SECOND or SUBSEQUENT preliminary amendment. A substitute specification. A change of power of attorney and/or address letter.

U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

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and all claims satisfied provisions of PCT Article 33(2)-(4)92.00 \$96.0							
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 a. [X] A check in the amount of \$970.00 to cover the above fees is enclosed. b. [] Please charge my Deposit Account No in the amount of \$ to cover the above fees. A duplicate copy of this sheet is enclosed. c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No A duplicate copy of this sheet is enclosed. 							
NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.							
SEND ALL CORRESPONDE Evenson, McKeown, Ed 1200 G Street, N.W., Su Washington, D.C. 20000 Tel. No. (202) 628-8800 Fax No. (202) 628-8844	wards & Lenahan, P.L.L ite 700 5	C.	for !	SIGNATURE J. D. Evans NAME 26,269 REGISTRATION N 13 May 1999	Lay 39015 TUMBER		

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Attorney Docket: 1920/47784

PATENT

In re National Stage Patent Application of

Dietmar KUBEIN-MEESENBURG et al.

Serial No.: PCT/EP97/06315

Filed: November 12, 1997

For: ARTIFICIAL JOINT, IN PARTICULAR ENDOPROSTHESIS FOR

REPLACING NATURAL JOINTS

PRELIMINARY AMENDMENT

Box PCT

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

Preliminary to examination of the above-captioned PCT national stage application, as amended during International Preliminary Examination, kindly further amend the application as follows:

IN THE CLAIMS

Claim 3, line 1, delete "according to one of claims 1 or 2" and insert in lieu thereof --according to claim 1--.

Claim 4, line 1, delete "according to one of the claims 1 through 3" and insert in lieu thereof --according to claim 1--.

IN THE ABSTRACT:

After the claims, please insert the Abstract of the Disclosure found on the accompanying sheet.

REMARKS

The foregoing amendments are respectfully submitted to eliminate multiple dependencies from the claims prior to

calculation of the filing fee, and to add the required abstract of the disclosure.

Entry of the amendments and favorable action on the application are earnestly solicited.

Respectfully submitted,

May 13, 1999

J. D. Evans

Registration No. 26,269

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Abstract of the Disclosure

The invention concerns an artificial joint, in particular an endoprosthesis for replacing natural joints, comprising at least two artificial joint parts with curved articulation faces, a curved contact line being formed on each of the articulation The curved contact line (L1) of one of the articulation faces is part of an elliptical section contour of a first cylinder (1) or cone having the cylinder radius (R1) or the cone The other contact line (L2) takes the form of a counter track of a second cylinder (2) or second cone having the cylinder radius (R2) or the cone angle (α 2) and rolling and/or sliding on the first cylinder (1) or first cone. articulation faces comprise control faces (F1, F2) formed from a plurality of straight contact lines (B). On one side, these control faces (F1, F2) adjoin the contact lines (L1, L2) opposite one another, and each of the contact lines is the connection line between an instantaneous contact point (K) of the contact lines and an instantaneous common point (Q) instantaneous pole of the respective movement systems in a reference plane (X, Y) or a reference sphere in the moved/unmoved system.

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Artificial Joint, in Particular Endoprosthesis for Replacing Natural Joints

The invention presented relates to an artificial joint, in particular an endoprosthesis for replacing natural joints, comprising at least two artificial joint parts, each with curved articulation faces on which the joint parts articulate with respect to one another.

Such an artificial joint is known from the German patent application P 42 02 717.9. In it, the joint faces have different circular section contours in planes which are perpendicular to each other, namely one longitudinal plane and a transverse plane, where the ratios of curvature for the articulation faces in each of the planes are convex-convex, convex-concave or concave-concave, and the geometry of the joint's articulation faces with respect to one another is determined in each of the two planes by a joint chain with two joint axes, a so-called dimeric joint chain, which runs through the centers of curvature of the articulation faces of their respective section contours. Since the articulation faces of this artificial joint are formed convexconcave, concave-concave or convex-convex, essentially point-like load transmission regions come into being so that increased surface pressures can occur on the articulation faces which lead to wearing away of material. This can shorten the life span of these artificial joints. In order to improve the load transmission between the articulation faces of the parts of the joint, it is suggested in the known joint to arrange a pressure distribution body between each of the individual parts of the joint with which a better and more even distribution of pressure is achieved. However, this pressure distribution body increases the number of required joint parts for the artificial joint.

The object of the invention presented is to create an artificial joint in which point-like load transmission regions are avoided and which it is not necessary to fit with pressure distribution bodies and which at the same time conforms optimally to the conditions of the human body when used as an endoprosthesis, particularly substituting a natural human joint.

According to the invention, this is achieved with an artificial joint of the kind described in the introduction, where on each of the articulation faces a curved contact line is formed, and the curved contact line of one of the articulation faces is part of an

elliptical section contour of a first cylinder or a cone having the cylinder radius R1 or respectively the cone angle $\alpha 1$, and the other contact line takes the form of a counter track of a second second [sic] cylinder or second cone having the cylinder radius R2 or respectively the cone angle $\alpha 2$ and rolling and/or sliding on the first cylinder or first cone; also the articulation faces comprise control faces formed from a plurality of straight contact lines, and, on one side, these control faces adjoin the contact lines opposite one another, and each of the contact lines is the connection line between an instantaneous contact point of the contact lines and an instantaneous reference point of the respective movement systems in a reference plane or on a reference sphere in the moved/unmoved system. In accordance with the invention, a fixed or moving point of the moved or unmoved system will preferably be chosen as reference point, where it is assumed that one of the cylinders or cones is stationary and the other cylinder or cone rolls and/or slides on this stationary cylinder/cone.

The restriction to an unavoidable motion and the choice of the instantaneous pole of rotation as reference point cause, since the pole curves roll on each other without sliding, this characteristic to be transmitted to corresponding sections of the control faces. If, instead of the instantaneous center of revolution, another instantaneous common point is used from the reference plane or reference sphere in the moved or unmoved system, the ratio of rolling to gliding can thereby be varied.

According to the invention, it is further provided that the first and the second cylinder or the first and the second cone are arranged with respect to each other so that they form a straight dimeric joint chain or an overlaid dimeric joint chain. For cylinders in a straight dimeric chain, the relationship R = R2 + R1 applies or, in an overlaid dimeric chain, the relationship R = R2 - R1, where R is the radius of the joint's axial path and R1 the radius of the first cylinder and R2 the radius of the second cylinder. In the case of the cone, analogous to the cylinders, $\alpha = \alpha 2 + \alpha 1$ and $\alpha = \alpha 2 - \alpha 1$ apply, where α is each of the angles between the axes of the tangential cone pairs.

Since, according to the invention, the cylinders or cones roll or slide on or in each other and the distance between the cylinder axes or the angle between the cone axes remains constant, a flat or spherical dimeric chain results. Thus, the motion, in principle having three parameters and possible as flat or spherical, is limited to two

degrees of freedom. The corresponding radii of the cylinder or angles of the cone are preferably adapted to the anatomical conditions of the human knee joint, however can also be changed according to the materials used and their characteristics.

The artificial joint according to the invention distinguishes itself in that a linear load transmission region is formed in every contact point of the articulation faces.

Furthermore, it can be advantageous according to the invention if next to the region of direct load transmission a region without any touching contact is formed in the region of the control faces, such that in action the surrounding tissue is only minimally injured. Therefore, according to the invention it is advantageous if, on the side of the contact lines opposite the control faces, the contact lines are extended arched in bowed lines so as to form toric surfaces. The bowed lines are defined in that at the instantaneous contact point of the contact lines in the moved or unmoved system a plane is formed which stretches from the respective contact line of the control faces and the common perpendiculars of the contact lines to a tangent of one of the contact lines at the respective contact point. The toric surfaces are formed such that the outer part of the toric surfaces' articulation faces don't touch each other. These outer parts of the toric surfaces form the curved articulation faces' region of indirect load transmission.

According to the invention, the bowed lines are attached to their respective contact lines of the control face without any kink, and their normal lines coincide at the contact point. By advantageously forming the bowed lines in circularly bow-shaped sections - if differently sized radii are chosen in the outer sections – a free space can always be maintained between the articulating toric surfaces during the moving of the articulation faces.

Preferably, the joint according to the invention is used in a four-joint as an endoprosthesis for the human knee such that the medial joint compartment forms the overlaid dimeric chain, and the lateral joint compartment the straight dimeric chain, whereby a four-joint is inevitably formed.

Using the exemplary embodiments shown in the enclosed drawings, the invention will be explained in detail.

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Figures 1 through 11 show the construction of joints according to the invention.

According to the invention presented, a particular flat or also spherical controlled movement should be achieved. This is achieved in that a flat or spherical linkage is provided. In this linkage, the rotational axes are replaced in a first step by cylinders, arranged around these axes, which touch each other or by spherical cones, where these cylinders or cones roll and/or slide on each other. The corresponding radii of the cylinders or the cone angles of the cones are adapted to the anatomical conditions of the natural joint to be replaced, in particular the human knee joint.

In Fig. 1 two cylinders 1, 2 are shown which roll and slide on each other and have the midpoints M1 and M2 and the radii R1 and R2 and the rotational axes D1 and D2. The pair of cylinders shown is arranged as a flat, straight dimeric chain, so that cylinder 2 rolls or slides on cylinder 1. R = R2 + R1 applies, where R is the radius of the joint's axial path, also the length of the dimeric joint chain. Fig. 1a shows a representation of two cones 1, 2 rolling on each other and having their respective cone angles α 1, α 2, where $\alpha = \alpha$ 2 + α 1 applies.

In Fig. 2 a cylinder arrangement is shown of cylinders 1 and 2, midpoints M1 and M2, radii R1 and R2 and cylinder axes D1 and D2, where these cylinders are arranged in the form of an overlaid dimeric chain. Here, R = R2 - R1 applies, where R is again the radius of the joint's axial path and therefore the length of the dimeric chain. Fig, 2a shows a representation of two cones 1, 2 rolling inside each other and having their respective cone angles $\alpha 1$, $\alpha 2$, where $\alpha = \alpha 2 + \alpha 1$ is.

As shown in Fig. 2, in this arrangement, for example, cylinder 1 is chosen as the stationary piece, where, by cutting through cylinder 1 at an angle, a contact line L1 is chosen on cylinder 1 which thus has an elliptical form. Cylinder 2 is chosen as the moving piece and rolls and/or slides now on cylinder 1, where on the cylinder surface a counter-curve forms as contact line L2 as a function of the rolling and sliding motion of cylinder 2. This contact line 2 has a curve-like form, seen section-wise. Therefore, both contact lines L1 and L2 have at any given instant a common contact point K. According to the invention, cylinder 1 can, for instance, be assigned as the

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femural joint piece of the inventive knee in the construction of an artificial joint, and cylinder 2 as the tibial joint part.

In Fig. 3 it is shown how now, in the joint arrangement according to Fig. 2, based on contact lines L1 and L2, which are formed on cylinders 1 and 2, contact lines B, which require linear contact, are produced for generating control faces according to the invention. Here, a basis point Q is advantageously fixed in the moved system, being randomly chosen in a reference plane (sagittal plane) that is shifted to the interior of the joint such that at the instantaneous contact point K of the contact lines L1 and L2 the connection line B advantageously forms an angle β (35° < β < 70°) with respect to the z axis. This reference plane lies parallel to the functional plane, here represented by the coordinate plane x and y. The sum of the contact lines B in the resting system produces a control face F1 having lines running between contact line L1 and path 5 of the basis point Q (see picture 4). In the moved system, a control face F2 arises between contact line F2 and basis point Q, stationary in this system (see picture 5). Therefore, in every state of motion, both control faces F1 and F2 each move linearly in accordance with their design. For each of the joint surfaces a part of the control faces F1 and F2 is chosen which adjoins L1 or L2 and extends a maximum of 3 cm, measured from the contact line to the middle. These parts of the control faces F1 and F2 formed by the contact lines B belong to the region of direct load transmission.

Furthermore, it is provided according to the invention that articulating partial faces with indirect load transmission are produced on the side of the contact lines L1, L2 opposite the control faces F1, F2. The design required for that and in accordance with the invention is explained using Figure 6. At the instantaneous contact point K of the contact lines L1, L2, an instantaneous plane is set up as an aide in the moved and the unmoved system and stretches from the contact line B of the control faces F1, F2 and a common perpendicular 7 of the contact line B and a tangent t of the contact line L1 and/or L2. In this plane, bow-shaped curves, bowed lines S1, S2, which advantageously remain the same throughout their progression, are attached without any kink to the contact line B of the control faces F1, F2. In the moved system, as is shown in Fig. 7, and in the unmoved system, as is shown in Fig. 8, toric surfaces 9, 10 are thereby produced which are attached to their respective control faces F1, F2

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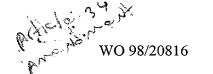
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without any kink and whose normal lines coincide at the contact point. The bowshaped curves S are made such that during motion free space always remains between the articulating toric surfaces 9, 10 which they form. This can be achieved with the circular bowed lines S1, S2 by choosing different sized radii. Furthermore, it can be advantageous to provide S1 and S2 with a common radius over a certain distance (up to maximum 2 cm) and only then, without any kink, to introduce differently sized radii. The region of direct load transmission is thereby extended into the bow-shaped region. Since the control faces F1 and F2 and the toric articulation faces 10, 9 come about due to the motion of an elliptical section contour comprised of lines and curves, these faces can be produced using a CNC grinding machine. Basis point Q can also be defined in the unmoved system. It can further be advantageous to choose Q depending on the motion and particularly to use for this the instantaneous center of revolution P (picture 6) which lies in a random intermediate plane. The control face F1 lies, then, between contact line L1 and the resting pole path 4, and the control face F2 lies between contact line L2 and the moving pole path 6. Resting pole path 4 and moving pole path 6 arise as intersection lines of this randomly chosen plane with the sum of the instantaneous rotational axes of the motion. If the instantaneous center of revolution is chosen to produce the contact lines B, sliding is minimized on the formed control faces F1 and F2 since the pole curves roll on each other. If, instead of the instantaneous center of revolution, another instantaneous common point in a reference plane in the moved/unmoved system is used, the ratio of rolling and sliding can be varied.

Fig. 9 shows the transfer of the unmoved system's configuration from the control face F1 with attached toric surface 10 according to Fig. 8 to an artificial joint part 12 which can form the articulation face of a joint's head. It is to be noted here that the dimensions of the faces F1 and 10 are adapted to the anatomical conditions.

A joint according to the invention is formed advantageously as an endoprosthesis for replacing the human knee joint from by coupling two joint arrangements according to the invention as shown in Fig. 1 and 2. Here, the control faces of each pair of joint bodies are arranged with respect to a mid-plane X-X such that they lie on the side facing the mid-plane X-X. The tibial joint body and the femural joint body here are each fixed immovably with regard to each other. Thus, a compulsory characteristic arises which is determined by the resultant four-joint. In the side view the

instantaneous center of revolution results as an intersecting point of the lateral and medial chain (or their extensions). In all, the resting pole path is created in the stationary plane and the moving pole path is created in the moved plane. For a knee joint of the right knee seen from behind, figures 10 and 11 show the femural articulation faces and tibial articulation faces of the lateral joint compartment 11 and the medial joint compartment 12 which are produced according to the design process in accordance with the invention. In the regions of the indirect load transmission, that is the toric articulation faces 9, 10, the radii are chosen such that tibial sized radii are provided for femurs. In the lateral joint compartment 11, an arrangement according to Fig. 2 is formed, namely a straight dimeric joint chain, and in the medial joint compartment 12 an overlaid dimeric joint chain is provided according to Fig. 1.



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Patent claims

1. Artificial joint, in particular endoprosthesis for replacing natural joints, comprising at least two artificial joint parts with curved articulation faces,

where a curved contact line is formed on each of the articulation faces; the curved contact line (L1) of one of the articulation faces is part of an elliptical section contour of a first cylinder (1) or cone with the cylinder radius (R1) or respectively cone angle (α 1), and the other contact line (L2) takes the form of a counter track of a second second [sic] cylinder (2) or second cone having the cylinder radius (R2) or respectively the cone angle (α 2) and rolling and/or sliding on the first cylinder (1) or first cone,

where the joint is designed as a flat or spherical four-joint, whose reference plane or reference sphere, [sic] lie in the resting or moving pole curve, is chosen such that it lies between the condyles to be constructed, and where the first cylinder or cone represents the unmoved system and the other cylinder which rolls or slides represents the moved system,

where a straight contact line B, in which the moved and the unmoved system touch instantaneously, is drawn from a respective contact point (K), which lies on the curved contact lines, to a fixed chosen point Q, which belongs to the moved system or to the unmoved system and lies in a sagittal plane which is shifted to the joint interior and chosen randomly, or to the instantaneous center of revolution P on the resting or moving pole curve,

where the plurality of the contact lines B form a control face F1 of the unmoved system and a control face F2 of the moved system, and the control faces each represent one of the joint faces of one of the two sides of the four-joint,

and where the second joint side is designed accordingly.

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2. Artificial joint according to claim 1, characterized in that the first and the second cylinders (1, 2) or the first and the second cones (1, 2) are arranged with respect to each other such that they form a straight dimeric joint chain having the relationship R = R2 + R1 or an overlaid dimeric joint chain having the relationship R = R2 - R1, where R is the radius of the joint's axial path of the dimeric joint chain and R1 the radius of the first cylinder (1), where in the case of the spherical arrangement, α = α2 + α1 results for the first cone pair and α = α2 - α1 for the second cone pair,

3. Artificial joint according to one of claims 1 or 2, characterized in that on the side of the contact lines (L1,L2) opposite the control faces (F1, F2), the contact line (B) are [sic] extended in a curve such that toric surfaces (9, 10) are formed, where the bowed lines are defined in that at the instantaneous contact point (K) of the contact lines (L1,L2) a plane is set up in the moved and unmoved system which stretches from the respective contact lines (B) of the control faces (F1, F2) and the common perpendicular (7)

based on the cone angles $\alpha 1/\alpha 2$.

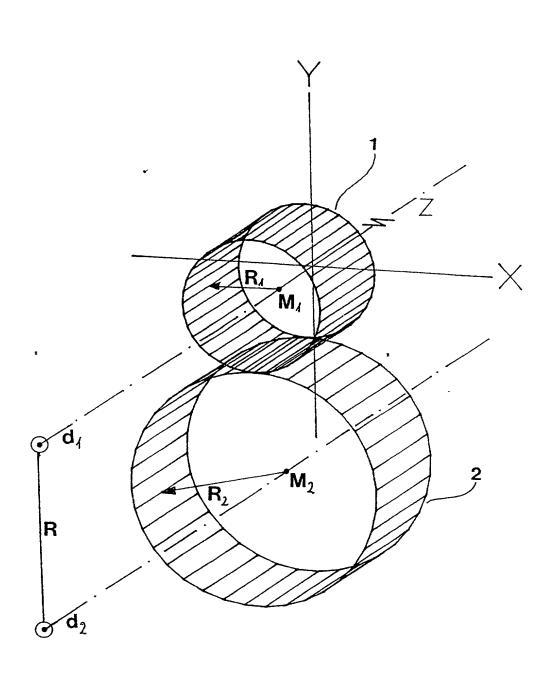
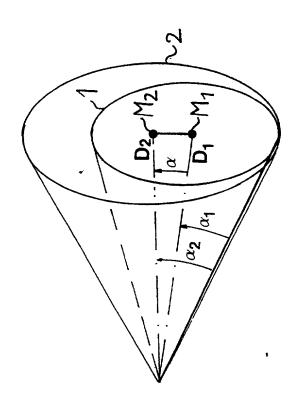
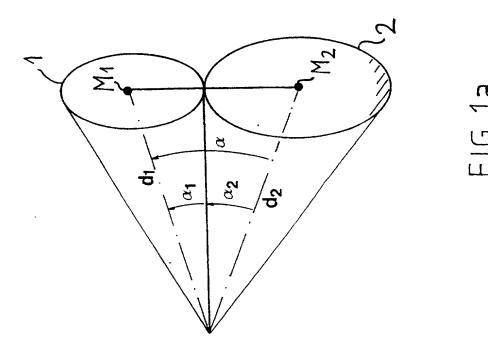


FIG.1





F1G.2a



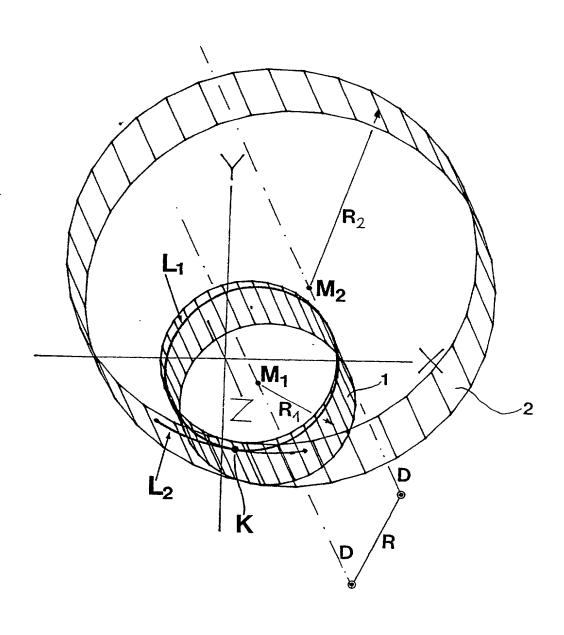


FIG.2

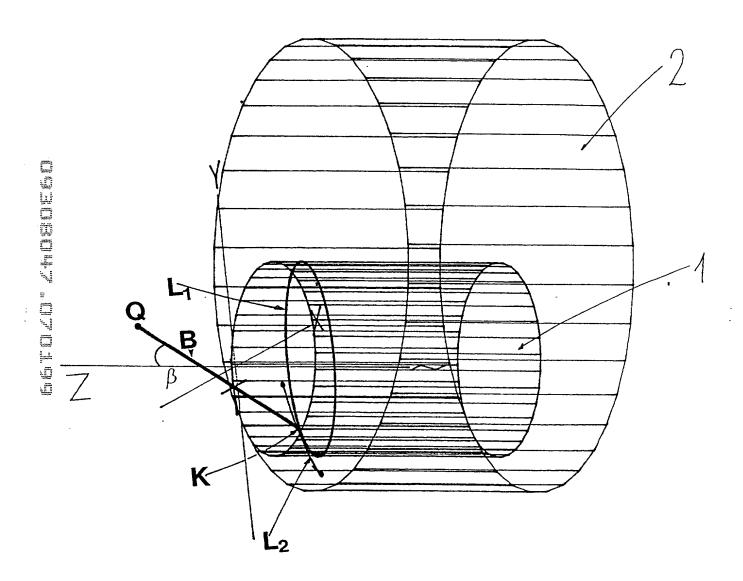


FIG.3

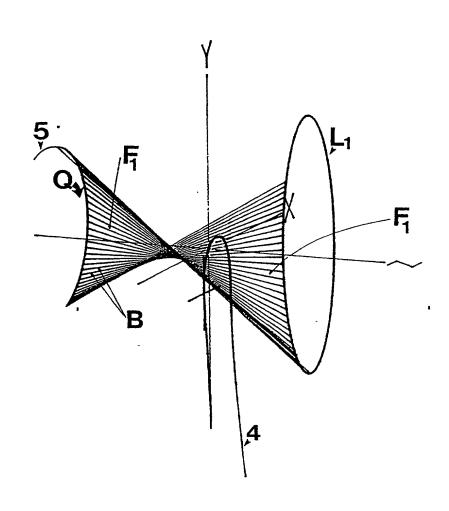
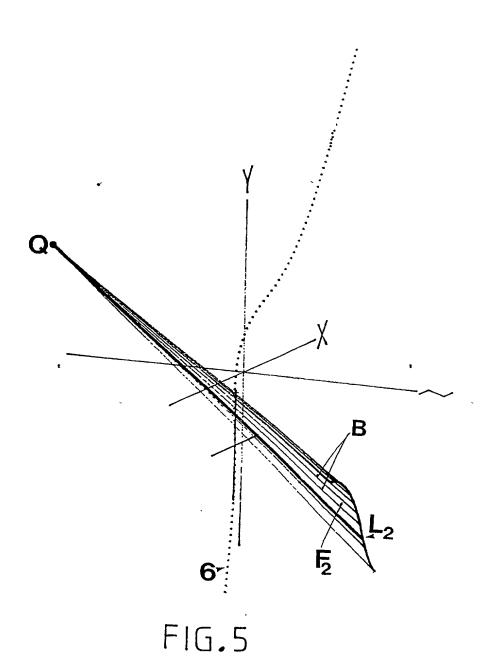
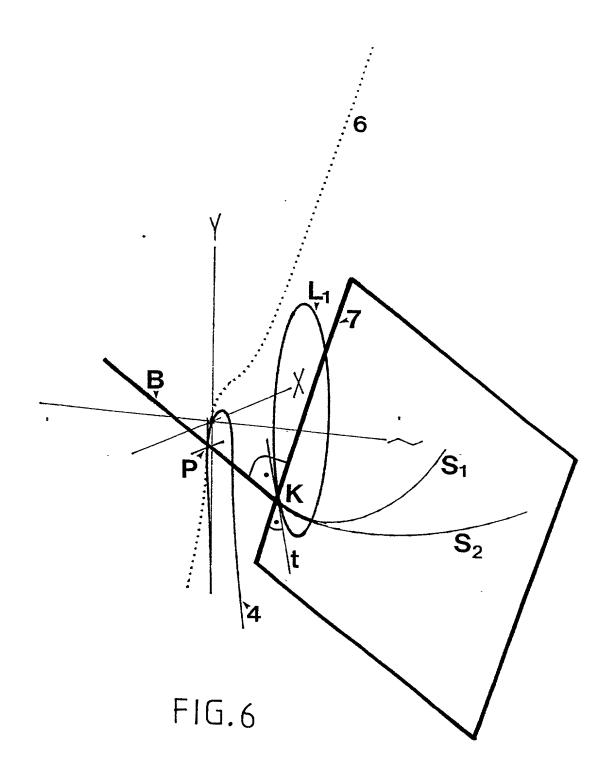


FIG.4







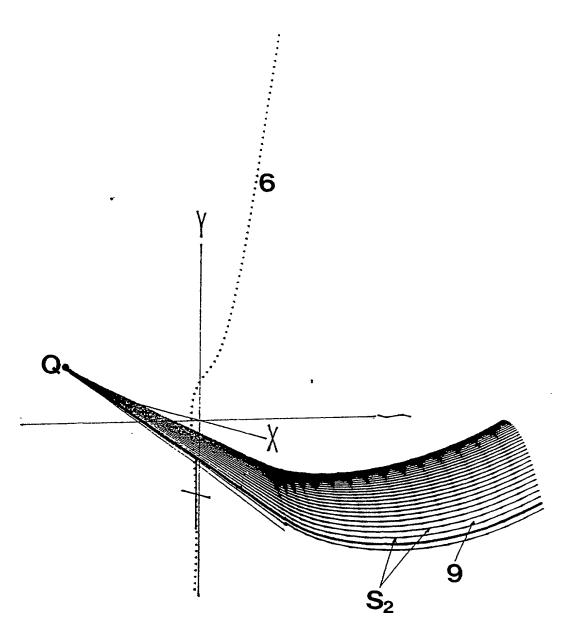


FIG.7

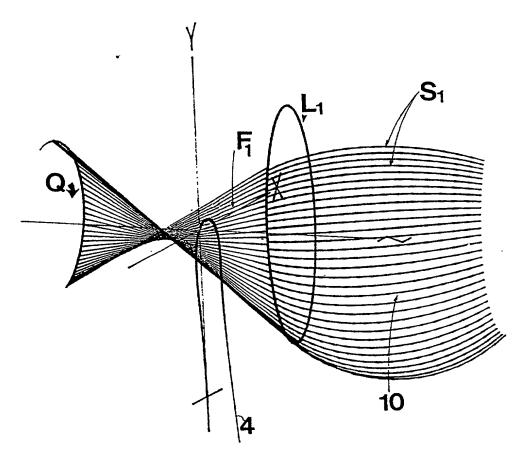
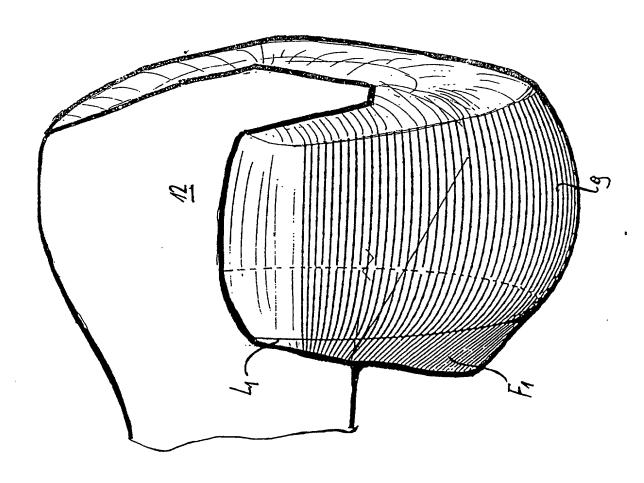


FIG.8

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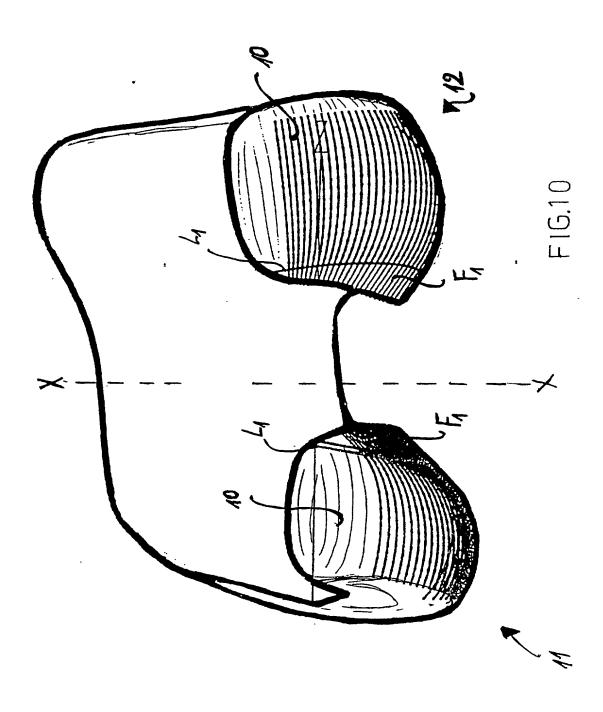
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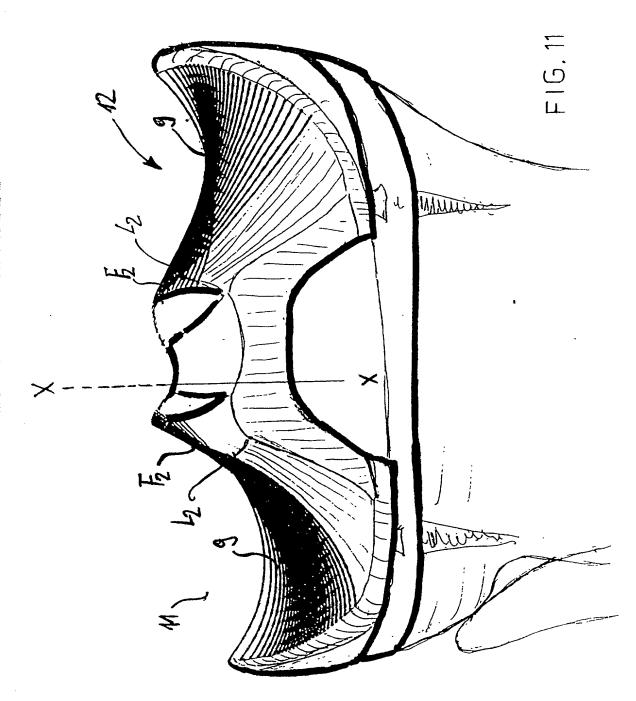
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Attorney Docket No. 1920/47784

DECLARATION AND POWER OF ATTORNEY - PATENT APPLICATION

As a below named inventor, I hereby declare that my citizenship, postal address and residence are as stated below; that I verily believe I am the original, first and sole inventor (if only one inventor is named below) or a joint inventor (if plural inventors are named below) of the invention entitled:

inventor (if only one named below) of the in		below) or a	joint inventor (if	plural inventors are
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was amend	ded on <u>15 Jan.</u>	1999 (if a	applicable).	
I hereby state that specification, included acknowledge the duty defined in 37 CFR §1.5 Code §119 of any fore have also identified a filing date before	ding the claims, to disclose all i 6. I hereby claim ign application(s) below any foreign a	as amended information foreign prio for patent upplication f	by any amendment reknown to be materia rity benefits under T or inventor's certif for patent or invento	eferred to above. I l to patentability as litle 35, United States icate listed below and r's certificate having
Post our Providence Board description	+ i / -)			Priority Claimed
Prior Foreign Applica		~	10.37 1006	
196 46 891.4			<u>13 Nov. 1996</u>	
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(Number)	(Country	y)	(Day/Month/Year)	
I hereby claim the beapplication(s) listed application is not distributed the first paragraph of all information known available between the filing date of this applications.	below and, insofa sclosed in the price f Title 35, United to be material to filing date of the	r as the sub or United St States Code	oject matter of each ates application in , §112, I acknowledg	of the claims of this the manner provided by e the duty to disclose
(Application Serial N		(Filing Da		(Status)
I hereby appoint as p Reg. No. 26,160; Gary I. Cantor, Reg. No. 24 business in the Pater United States and int	R. Edwards, Reg. 1,392, and Jeffrey it and Trademark O	No. 31,824: D. Sanok, Re ffice connec	Joseph D. Evans, Reg. No. 32,169 to pros ted with this applic	g. No. <u>26,269;</u> Herbert secute and transact all cation and any related
Ev	-	-	& Lenahan P.L.L	.c.
	1200 G St	reet, N.W.	, Suite 700	
	Washir	gton, D.C	. 20005	
	Telepho		628-8800	
	racsimi.	re: (202)	628-8844	
statements made on in statements were made of punishable by fine or	nformation and bel with the knowledge imprisonment, or b false statements	lief are bel that willfu ooth, under §	ieved to be true; a L false statements ar 1001 of Title 18 of t	are true and that all nd further that these nd the like so made are the United States Code, the application or any
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